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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,740	12/14/2001	Raman K. Bakshi	19526PR	9687
210	7590	12/16/2003	EXAMINER	
MERCK AND CO INC P O BOX 2000 RAHWAY, NJ 070650907			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/020,740	BAKSHI ET AL.
	Examiner Brenda L. Coleman	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4,5 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 22 is/are allowed.
- 6) Claim(s) 1,4,5,11-21,23 and 24 is/are rejected.
- 7) Claim(s) 25 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1, 4, 5 and 11-25 are pending in the application.

Reissue Applications

1. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
2. In accordance with 37 CFR 1.175(b)(1), if the claims or specification are further amended during the prosecution of this reissue, a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."
3. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).
4. The amendment filed December 14, 2001 proposes amendments to claims 1, 4 and 5 that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

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- a) Claim 1 includes text and/or a moiety, i.e. R¹ is **selected from methyl and ethyl**, which is being deleted but does not appear as it does in claim 1 of U.S. 6,001,844. The definition of R¹ should read R¹ is [selected from] methyl [and ethyl].
- b) Claim 4 includes text and/or a moiety, i.e. halo (**F,Cl, Br, I**) which is being added but does not appear as it does in claim 4 of U.S. 6,001,844.
- c) Claim 5 includes text and/or a moiety, i.e. [and] which is being deleted but does not appear as it does in claim 5 of U.S. 6,001,844.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1, 4, 11-19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) Claim 1 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the semi-colon separating the (2) and (3) moieties in the definition of the substituents on the phenyl ring, where the other moieties are separated by a comma.
- b) Claim 1 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the second occurrence of alkoxy, i.e. (7) and (10). The definition of alkyloxy (or alkoxy) in the specification represents an alkyl group having the indicated number of carbon atoms attached through an oxygen bridge, however, there

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is not indicated number of carbon atoms. Additionally, C₁₋₂ alkyloxy is of a narrower scope than the alkyloxy of (10).

c) Claim 1 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the definition of the substituents on the steroid ring which does not terminate with an "and" before the last variable.

d) Claim 1 (and claims dependent thereon) are vague and indefinite in that it is not known what is meant by the last moiety in the list of substituents on the phenyl ring which is alkyloxy. It is believed that the applicants intended alkyloxy.

e) Claim 4 is vague and indefinite in that it is not known what is meant by the moiety pyrizinyl. It is believed that the applicants intended pyrazinyl.

f) Claim 4 is vague and indefinite in that it is not known what is meant by the semi-colon separating the (2) and (3) moieties in the definition of the substituents on the phenyl ring, where the other moieties are separated by a comma.

g) Claim 13 is vague and indefinite in that it is not known what is meant by the species labeled (l) which lists two species.

h) Claim 13 is vague and indefinite in that it is not known what is meant by the labeling of the species such that the (m) is missing, i.e. (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l) and (n).

i) Claim 14 is vague and indefinite in that it is not known what is meant by the semi-colon separating the (2) and (3) moieties in the definition of the substituents on the phenyl ring, where the other moieties are separated by a comma.

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j) Claim 15 is vague and indefinite in that it is not known what is meant by the semi-colon separating the (2) and (3) moieties in the definition of the substituents on the phenyl ring, where the other moieties are separated by a comma.

k) Claim 16 is vague and indefinite in that it is not known what is meant by the species labeled (b) which lists two species. It is believed that the applicants intended a line break after the species labeled (b) and before the species labeled (c).

l) Claim 17 is vague and indefinite in that it is not known what is meant by the semi-colon separating the (2) and (3) moieties in the definition of the substituents on the phenyl ring, where the other moieties are separated by a comma.

m) Claim 17 is vague and indefinite in that it is not known what is meant by the second occurrence of alkoxy, i.e. (7) and (10). The definition of alkyloxy (or alkoxy) in the specification represents an alkyl group having the indicated number of carbon atoms attached through an oxygen bridge, however, there is not indicated number of carbon atoms. Additionally, C₁₋₂ alkyloxy is of a narrower scope than the alkoxy of (10).

n) Claim 17 is vague and indefinite in that it is not known what is meant by the last moiety in the list of substituents on the phenyl ring which is alkoxy. It is believed that the applicants intended alkyloxy.

o) Claim 18 is vague and indefinite in that it is not known what is meant by the semi-colon separating the (2) and (3) moieties in the definition of the substituents on the phenyl ring, where the other moieties are separated by a comma.

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p) Claim 19 is vague and indefinite in that it is not known what is meant by the species labeled (g) which lists two species. It is believed that the applicants intended a line break after the species labeled (g) and before the species labeled (h).

q) Claim 23 is vague and indefinite in that it is not known what is meant by the species labeled (g) which lists two species. It is believed that the applicants intended a line break after the species labeled (g) and before the species labeled (h).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4, 5, 11-13, 17-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GORMLEY et al., WO 92/16213. The generic structure of GORMLEY encompasses the instantly claimed compounds (see Formula II, page 7) as claimed herein. An example such as the one spanning lines 3-4 of page 9 differ only in the nature of the optional double bond, R¹ and R² substituents. Page 8, lines 2-8 define the substituent R¹ as methyl and ethyl and R² as a phenyl, optionally substituted by methyl, chloro or fluoro. Compounds of the instant invention are generically embraced by GORMLEY in view of the interchangeability of optional double bond, R¹ and R² substituents of the tetracyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example 2-methyl, 2-chloro or 4-chlorophenyl as well as other possibilities from the generically

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disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

7. Claims 1, 4, 5, 11-13, 17-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over RASMUSSEN et al., WO 94/15602. The generic structure of RASMUSSEN encompasses the instantly claimed compounds (see Formulae I and Ia, pages 4 and 5) as claimed herein. An example such as the one in line 19 of page 6 differs only in the nature of the optional double bond, R¹ and R² substituents. Page 8, lines 2-8 define the substituent R¹ as methyl and ethyl and R² as a phenyl, unsubstituted or substituted by one or two of methyl, chloro or fluoro. Compounds of the instant invention are generically embraced by RASMUSSEN in view of the interchangeability of the R¹ and R² substituents of the tetracyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example 2,5-dichlorophenyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

8. Claims 1, 4, 5, 11-13, 17-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over RASMUSSEN et al., WO 94/07861 (U.S. 5,693,810). The generic structure of RASMUSSEN encompasses the instantly claimed compounds (see Formula I, page 2) as claimed herein. Example such as the ones spanning lines 23-30 of page 8 differ only in the nature of the optional double bond, R, R¹, X, Y and Z substituents. Page 3, line 2 through page 4, line 12 define the substituent R as H, CH₃, or C₂H₅; R¹ as H, C₁-C₁₀ alkyl or phenyl; and X, Y and Z independently represent -H; -OH; -NH₂; SH; SC₁-C₄ alkyl; -CO₂H; -CN; etc. Compounds of the instant invention are generically embraced by RASMUSSEN in view of the interchangeability of the R, R¹, X,

Y and Z substituents of the tetracyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example 4-methyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

9. Claims 1, 4, 5, 11-13, 17-21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over BATCHELOR et al., WO 95/07926 (U.S. 5,998,427). The generic structure of BATCHELOR encompasses the instantly claimed compounds (see Formula I, page 3) as claimed herein. Examples 22, 23, 38, 42, 44, 45, 46, 49, etc. differ only in the nature of the optional double bond, R¹, R² and R³ substituents. Page 3, line 25 through page 5, line 9 define the substituent R¹ as hydrogen or methyl; R² is hydrogen or methyl; and R³ is (A) or (B) where (B) is a phenyl ring substituted by R⁶, R⁷, R⁸ and X, wherein R⁶ is trifluoromethyl, phenyl optionally substituted with one or more halogens or branched (C₄₋₇) alkyl groups, or branched (C₄₋₇) alkyl; either R⁷ or R⁸ is trifluoromethyl, halogen, phenyl optionally substituted with one or more halogens or branched (C₄₋₇) alkyl groups, or branched (C₄₋₇) alkyl, while the other is hydrogen or halogen; and X is hydrogen or halogen. Compounds of the instant invention are generically embraced by BATCHELOR in view of the interchangeability of the R¹, R², R³, R⁶, R⁷, R⁸ and X substituents of the tetracyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example 4-methyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Applicants' should also note that claimed subject matter is involved. Two patents cannot issue to the same invention. Applicants' are required to show patentable differentiation of the claimed subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 4, 17 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,693,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the instant invention are embraced by the claims of U.S. '810.

11. Claims 1, 4, 11, 12, 14, 15, 17, 18 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22 and 25 of U.S. Patent No. 6,645,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds,

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compositions and method of use of the instant invention are embraced by the claims of U.S. '974.

Claim Objections

12. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

13. Claim 22 is allowed. None of the prior art of record or a search in the pertinent art area teaches the compound as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 703-305-1880. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
December 12, 2003